

### REMARKS

Applicants respectfully requests entry of the amendments and remarks submitted herein. Claims 1-11, 14, 17, 22, and 25 have been canceled without prejudice to continued prosecution. Claims 12, 13, 15, 16, 20, and 21 have been amended herein.

Claims 12, 13, 15, 16, 18-21, 23, and 24 are currently pending. Attached is a marked-up version of the changes being made by the current amendments. Reconsideration of the pending application is respectfully requested.

#### Objections to the Claims

The Examiner has objected to claims 12, 13, 15, 16, 18-21, 23 and 24 for depending on a non-elected base claim. Applicants have amended claim 12 such that claim 12 is now an independent claim. Further, claims 13, 15, 16, 20, and 21 have been amended to reflect the proper dependency. Accordingly, Applicants respectfully request that the objection of claims 12, 13, 15, 16, 18-21, 23, and 24 be withdrawn.

#### Objections to the Specification

The specification stands objected to for inclusion of a web hyperlink. Applicants have amended the specification to remove the hyperlinks. Therefore, Applicants respectfully request that the objection to the specification be withdrawn.

#### The 35 U.S.C. §101 Rejections

Claims 12, 13, 15, 16, 19-21, 23 and 24 stand rejected under 35 U.S.C. §101 because the Examiner asserted that the claimed invention is directed to non-statutory subject matter. Applicants respectfully traverse this rejection.

The Examiner stated that the claims are drawn to a nucleic acid encoding a polypeptide that was known from *Brassica napus*. The Examiner also stated that the claims read on a product of nature given that the claimed nucleic acid is not isolated.

Applicants have amended claim 12 to recite "isolated." In addition, the Examiner's statement concerning the novelty of the claimed nucleic acid is incorrect. The claimed combinations of nucleic acids encode novel polypeptides, and the Examiner has not indicated where the claimed nucleic acid(s) could be found in nature. Applicants submit that claims 12, 13, 15, 16, 19-21, 23, and 24 are directed toward statutory subject matter, and respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

The 35 U.S.C. §112 Rejections

Claims 12, 13, 15, 16, 18-21, 23 and 24 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner stated that it is unclear what sequences would encode a protein having membrane anchoring properties, and particularly to what membrane. The Examiner further stated that the specification fails to describe what structural features are required to result in a protein having the claimed activity. Applicants respectfully refer the Examiner to page 9, line 16 through page 10, line 17, which describes what a membrane anchoring segment is; what kind of membrane the first polypeptide segment can anchor to; what characteristics of a polypeptide result in membrane anchoring; how membrane anchoring by a polypeptide can be evaluated; and numerous examples of membrane anchoring segments from known polypeptides. Applicants' specification meets the written description requirement with respect to the claimed first polypeptide segment having membrane anchoring properties.

The Examiner went on to state that it is unclear what functional activity the entire polypeptide would have, given the low percentage of sequence identity of the third polypeptide segment and given that the claim does not specify the functional activity for the claimed sequence. With respect to the functional activity of the entire polypeptide, Applicants respectfully refer the Examiner to page 13, line 17 through page 14, line 4, which describes what polypeptides of the invention can be used for regardless of whether or not the polypeptides form a desired reaction product at a desired rate. With respect to the third polypeptide segment, Applicants' specification discloses how to determine percent sequence identity (see, for example,

page 10, line 18 through page 11, line 25). Applicants' specification also discloses embodiments of the third polypeptide segment having particular residues or sequence motifs (see, for example, page 12, lines 4-23). In addition, Applicants provide eighteen different examples of polypeptides that have a third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4. The sequence identity for these eighteen different sequences ranges from 54% up to 100% relative to residues 115-506 of SEQ ID NO:4. See, for example, the even numbered sequences shown in SEQ ID NOs: 8-42. Therefore, the specification provides adequate written description for the third polypeptide segment of the claimed nucleic acid.

Applicants' specification meets the written description requirement with respect to the claimed nucleic acids. In view of the remarks and amendments herein, Applicants respectfully request that the rejection of claims 12, 13, 15, 16, 18-21, 23 and 24 under 35 U.S.C §112, first paragraph, be withdrawn.

Claims 12, 13, 15, 16, 18-21, 23 and 24 stand rejected under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. This rejection is respectfully traversed.

The Examiner stated that while the specification is enabled for isolated nucleic acids encoding polypeptides with membrane anchoring function from FAE of KCS polypeptides and polypeptides having the sequence of residues 75-114 of SEQ ID NOs:12 or 14, the specification is not enabled for nucleic acids encoding any membrane anchoring polypeptide and any sequence having 40% identity to residues 115-506 of SEQ ID NO:4.

As discussed above, the instant specification provides an abundance of disclosure on membrane anchoring properties, namely what membrane anchoring properties are, how polypeptides having membrane-anchoring properties are identified, and numerous examples of polypeptide sequences possessing membrane-anchoring properties. See page 9, line 16 through page 10, line 17.

Applicants also have enabled the third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4. Applicants respectfully refer the Examiner to page 10, line 18 through page 11, line 25, which describes how sequence identity can be

determined. In addition, Applicants describe numerous embodiments of the third polypeptide segment having particular sequence features. See, for example, page 12, lines 4-23. Furthermore, Applicants provide eighteen different examples of polypeptides having a third polypeptide segment, wherein the third polypeptide segment exhibits sequence identity to residues 115-506 of SEQ ID NO:4 ranging from 54% up to 100%. See, for example, the even numbered sequences shown in SEQ ID NOs: 8-42. Therefore, the specification is enabled for the third polypeptide segment of the claimed nucleic acid.

In view of the remarks and amendments herein, Applicants respectfully request that the rejection of claims 12, 13, 15, 16, 18-21, 23 and 24 under 35 U.S.C §112 be withdrawn.

Claims 20, 21, 23, and 24 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner indicated that claims 20 and 21 were confusing in the recitation of “a plant containing an exogenous nucleic acid.” Applicants have amended claims 20 and 21 to remove the reference to “exogenous” nucleic acid. Therefore, claims 20, 21, 23, and 24 are not indefinite, and Applicants respectfully request that the rejection of those claims under 35 U.S.C §112, second paragraph, be withdrawn.

#### The 35 U.S.C. §103 Rejections

Claims 12, 13, 15, 16, 18-21, 23 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over James et al. (WO 96/13582; hereafter ‘James’) taken with Clemens et al. (Accession No. AF009563, hereafter ‘Clemens’). This rejection is respectfully traversed.

The Examiner stated that James teaches a fatty acid elongase gene, and transformation of such a gene into host cells including both plant cells and yeast cells. The Examiner also asserted that James teaches a *B. napus* plant that inherently contains a fatty acid elongase coding sequence having a membrane anchoring polypeptide segment.

The Examiner asserted that Clemens teaches a nucleic acid that is 97.94% identical to the claimed second and third polypeptide segments, and that a polypeptide having membrane anchoring properties would be inherent in a fatty acid elongase sequence from *Brassica*.

Neither James nor Clemens teach or suggest a nucleic acid that encodes a polypeptide having the recited three segments. James or Clemens does not teach or suggest a nucleic acid encoding a polypeptide having a second segment that consists of residues 75-114 of SEQ ID NO:12 or 75-114 of SEQ ID NO:14. Nothing in James or Clemens teaches or suggests that the leucine (L) at residue 91 of the *Arabidopsis* FAE1 sequence can be changed to a cysteine (C) or that the lysine (K) at residue 92 can be changed to an arginine (R). Moreover, neither James nor Clemens teaches or suggests that polypeptides encoded by nucleic acids containing the above-indicated changes would have the enzymatic properties described in Tables 5 and 6 (see pages 25-26 of the specification).

The Examiner's argument that the sequence of Clemens has 97.94% sequence identity is not relevant to the pending claims. The claims recite that the second segment must have the sequence of residues 75-114 of SEQ ID NOs:12 or 14, and that the third segment have at least 40% sequence identity to residues 115-506 of SEQ ID NO:4. Therefore, the Clemens sequence reads on the third polypeptide segment of the claimed nucleic acid, but the Clemens sequence certainly does not teach or suggest the second polypeptide segment. Thus, the claimed nucleic acids are not obvious over James or Clemens.

Neither James nor Clemens teach or suggest the claimed nucleic acids. In view of the remarks and amendments herein, Applicants respectfully request that the rejection of claims 12, 13, 15, 16, 18-21, 23 and 24 under 35 U.S.C §103 be withdrawn.

Applicant : Jan G. Jaworski et al.  
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Page : 9

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CONCLUSION

Applicants ask that claims 12, 13, 15, 16, 18-21, 23, and 24 be allowed. Enclosed is a  
Enter \$ amount check for a One-Month Petition for Extension of Time fee. Please apply any  
other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

June 20, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

in the Specification:

The paragraph bridging pages 9 and 10 has been amended as follows:

The above-described polypeptides include a first polypeptide segment that can serve as a membrane anchor. Such a segment has properties that result in the elongase KCS polypeptide being anchored to a membrane, such as a lipid bilayer, detergent bilayer, micelle, or cell membrane. Possession of membrane anchoring properties may be the result of the primary structure, secondary structure and/or tertiary structure of the segment. For example, the segment may contain one or more transmembrane domain(s). Alternatively, a post-translational modification of an amino acid residue within the segment can result in the polypeptide being anchored to a membrane. Suitable modifications include, but are not limited to, covalent attachment of a lipid (*e.g.*, a glycosyl phosphatidylinositol anchor) or a carbohydrate (*e.g.*, an oligosaccharide). See, Alberts et al., *The Cell*, 2<sup>nd</sup> Edition, Garland Publishing, New York, pp 284-298 and Lodish et al., *Molecular Cell Biology*, 3<sup>rd</sup> Edition, Scientific American Books, p. 604 and pp. 688-692. The ability of a segment to serve as a membrane anchor can be demonstrated by observing whether a polypeptide having such a segment co-purifies with a membrane fraction. Alternatively, a segment can be a membrane-anchor if, after fusing it to the second and third segments, it is shown that the polypeptide possesses elongase KCS activity in an *in vitro* yeast microsome assay, since elongase KCS polypeptides are active when anchored to a membrane. As another alternative, computer algorithms, such as Predict Protein or META Predict Protein [(see [www.embl-heidelberg.de/predictprotein](http://www.embl-heidelberg.de/predictprotein))], can be used to predict the presence of a transmembrane domain within a segment, and hence, the ability of that polypeptide segment to serve as a membrane anchor.

The paragraph on page 10, lines 18-28 has been amended as follows:

A percent identity for any subject nucleic acid or amino acid sequence (*e.g.*, any of the fatty acid elongase chimeras described herein) relative to another "target" nucleic acid or amino acid sequence can be determined as follows. First, a target nucleic acid or amino acid sequence

of the invention can be compared and aligned to a subject nucleic acid or amino acid sequence, preferably using the BLAST 2 Sequences (BL2seq) program from the stand-alone version of BLASTZ containing BLASTN and BLASTP (e.g., version 2.0.14). The stand-alone version of BLASTZ can be obtained at Fish & Richardson's website or the National Center for Biotechnology Information (NCBI) website [[<www.fr.com>](http://www.fr.com) or [<www.ncbi.nlm.nih.gov>](http://www.ncbi.nlm.nih.gov)]. Instructions explaining how to use BLASTZ, and specifically the BL2seq program, can be found in the 'readme' file accompanying BLASTZ. The programs also are described in detail by Karlin et al. (*Proc. Natl. Acad. Sci. USA*, 87:2264 (1990) and 90:5873 (1993)) and Altschul et al. (*Nucl. Acids Res.*, 25:3389 (1997)).

In the Claims:

Claims 1-11, 14, 17, 22, and 25 have been canceled without prejudice. Claims 12, 13, 15, 16, 20, and 21 have been amended as follows:

12. (Amended) An isolated [A] nucleic acid encoding [the] a polypeptide, said polypeptide comprising in the amino-terminal to carboxy-terminal direction: [of claim 1]

(a) a first polypeptide segment, wherein said first polypeptide segment has membrane anchoring properties; joined to

(b) a second polypeptide segment having a sequence selected from the group consisting of residues 75-114 of SEQ ID NO:12 and residues 75-114 of SEQ ID NO:14; joined to

(c) a third polypeptide segment having at least 40% sequence identity to residues 115-506 of SEQ ID NO:4.

13. (Amended) The [A] nucleic acid [encoding the polypeptide] of claim [2] 12, wherein said third polypeptide segment has at least 50% sequence identity to residues 115-506 of SEQ ID NO:4.

15. (Amended) Host cells containing [a] the nucleic acid [encoding the polypeptide] of claim [1] 12.

16. (Amended) Host cells containing [a] the nucleic acid [encoding the polypeptide] of claim [2] 13.



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Serial No. : 09/877,476  
Filed : June 8, 2001  
Page : 12

Attorney's Docket No.: 07148-108001 / A15-549.01

20. (Amended) A plant containing [an exogenous] the nucleic acid [encoding the polypeptide] of claim [1] 12.

21. (Amended) A plant containing [an exogenous] the nucleic acid [encoding the polypeptide] of claim [2] 13.